

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

CAREDX, INC.,

and

THE BOARD OF TRUSTEES OF THE
LELAND STANFORD JUNIOR
UNIVERSITY,

Plaintiffs,

v.

NATERA, INC.,

Defendant.

C.A. No. 19-cv-567-CFC-CJB
(Consolidated)

JURY TRIAL DEMANDED

CAREDX’S ANSWER AND AFFIRMATIVE DEFENSES

CareDx, Inc. (“CareDx”), by and through its counsel, submits this Answer to the January 13, 2020 Complaint (“the Natera Complaint”) filed by Natera, Inc. (“Natera”) in C.A. No. 20-cv-38-CFC-CJB,¹ and demands a trial by jury.

NATURE OF THE ACTION²

1. CareDx expressly denies “infringing Natera’s patent” and that any of its activities constitute “infringement of Natera’s patented technology.” CareDx lacks information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 1 of the Natera Complaint and therefore denies them.

¹ Under the Court’s February 4, 2020 Order (D.I. 49), Case No. 20-cv-00038-CFC-CJB was consolidated with Case No. 19-cv-00567-CFC-CJB, with both cases using the consolidated caption used above.

² For the Court’s convenience, CareDx generally utilizes the same headings Natera used in the Natera Complaint. In so doing, CareDx does not admit that the headings are accurate, and CareDx reserves the right to contest any statements or characterizations contained in them.

2. Paragraph 2 contains statements of opinion to which no response is required. To the extent Paragraph 2 contains any factual allegations, CareDx denies them.

3. Paragraph 3 contains statements of opinion to which no response is required. To the extent Paragraph 3 contains any factual allegations, CareDx denies them.

4. Paragraph 4 contains statements of opinion to which no response is required. To the extent Paragraph 4 contains any factual allegations, CareDx denies them.

5. CareDx admits that U.S. Patent No. 10,526,658 (the “’658 patent”) states on its face that it is assigned to Natera, expressly denies that it infringes the ’658 patent, and denies the remainder of the allegations in Paragraph 5 of the Natera Complaint.

6. CareDx admits that the “’658 patent” on its face is assigned to Natera, and that the ’658 patent issued on January 7, 2020. CareDx lacks information sufficient to form a belief as to the truth of the remainder of the allegations in Paragraph 6 of the Natera Complaint and therefore denies them.

7. CareDx admits that Natera purports to seek monetary damages and injunctive relief but denies that it has any legal basis for doing so, and further denies that the ’658 patent is “valuable.”

THE PARTIES

8. CareDx admits that Natera is a Delaware corporation with its principal place of business at 201 Industrial Road, Suite 410, San Carlos, California 94070.

9. CareDx admits that it is a Delaware corporation with its principal place of business at 3260 Bayshore Boulevard, Brisbane, California 94005.

JURISDICTION AND VENUE

10. CareDx admits that Natera has filed a civil action for patent infringement that arises under the patent laws of the United States, but denies that Natera had a legitimate basis for doing so.

11. CareDx admits that this Court has subject matter jurisdiction over Natera's suit.

12. CareDx admits that it is subject to this Court's personal jurisdiction.

13. CareDx admits that it is subject to this Court's personal jurisdiction and that it offers AlloSure for sale throughout the United States. CareDx denies that it has infringed Natera's patent in this District or anywhere else.

14. CareDx admits that venue is proper in this district and that it is incorporated in this district.

FACTUAL BACKGROUND

Natera's History of Innovation

15. Paragraph 15 contains statements of opinion to which no response is required. To the extent Paragraph 15 contains any factual allegations, CareDx denies them.

16. Paragraph 16 contains statements of opinion to which no response is required. To the extent Paragraph 16 contains any factual allegations, CareDx denies them.

17. CareDx admits that Natera launched Prospera in 2019, and that Prospera is a cfDNA diagnostic test for evaluating organ transplant health. CareDx contends that the remainder of Paragraph 17 contains statements of opinion to which no response is required. To the extent Paragraph 17 contains any additional factual allegations, CareDx denies them.

18. Paragraph 18 contains statements of opinion to which no response is required. To the extent Paragraph 18 contains any factual allegations, CareDx denies them.

19. CareDx admits that Medicare issued a draft Local Coverage Determination (“LCD”) for Prospera in March 2019, and avers that the LCD speaks for itself. CareDx denies interfering in Natera’s commercialization efforts in any way. CareDx avers that the remainder of Paragraph 19 contains statements of opinion to which no response is required. To the extent Paragraph 19 contains any additional statements of fact, CareDx denies them.

20. CareDx lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 20 of the Natera Complaint and therefore denies them.

CareDx

21. Admitted.

22. Admitted.

23. CareDx denies the allegations contained in Paragraph 23 of the Natera Complaint, and further expressly denies infringement.

The ’658 Patent

24. CareDx does not dispute that the ’658 patent issued on January 7, 2020, is titled “Methods for Simultaneous Amplification of Target Loci,” and that Natera has correctly identified the alleged inventors named on the face of the ’658 patent. CareDx admits that USPTO records list Natera as the assignee of the ’658 patent. CareDx denies that the ’658 patent is directed to an invention. CareDx lacks information sufficient to form a belief as to the truth of the allegations in Paragraph 24 of the Natera Complaint and therefore denies them

25. CareDx does not deny that Natera has accurately reproduced the text of Claim 1 of the ’658 patent in paragraph 25 of the Natera Complaint.

26. CareDx denies that the alleged invention of the ’658 patent is novel, inventive, or worthy of patent protection in any way. CareDx avers that Natera’s allegations regarding what the claims of the ’658 patent are directed to is a legal conclusion to which no response is required.

To the extent Exhibit F has been properly incorporated by reference, as to the allegations regarding Dr. Quackenbush's background, CareDx lacks information sufficient to form a belief as to the truth of the allegations and therefore denies them. With respect to Dr. Quackenbush's statements regarding the ultimate question of patent eligibility, they amount to legal conclusions to which no response is required, and CareDx denies that the alleged invention of the '658 patent is novel, inventive, or worthy of patent protection in any way. To the extent there are any remaining factual allegations in paragraph 26 or Exhibit F, CareDx denies them.

[Response to "CareDx's Infringing Acts" Heading] CareDx denies that it has committed any infringing acts

27. Paragraph 27 contains no factual allegations; accordingly no response is required.
28. CareDx denies the allegations contained in Paragraph 28 of the Natera Complaint.
29. CareDx denies the allegations contained in Paragraph 29 of the Natera Complaint.
30. Admitted.
31. CareDx admits that the journal article referenced in paragraph 31 was published in 2016 and that it is referenced on CareDx's website. CareDx denies that this journal article provides a complete description of the operation of CareDx's AlloSure test and methodology as it pertains to Natera's infringement allegations.
32. CareDx denies that CareDx's AlloSure test infringes any claim of the '658 patent. To the extent Natera's reference to "Prospera" in Paragraph 32 can be understood to be a reference to CareDx's AlloSure product, CareDx denies that AlloSure operates in the manner Natera has set forth in Paragraph 32, and specifically denies that in AlloSure "the preamplified material is divided into multiple aliquots and further amplified using 48 limited complexity multiplexes with 1 to 11 targets per reaction." That AlloSure does not operate in this manner is reflected in documents it has produced in this litigation. *See, e.g.,* CAREDxNA00004885- CAREDxNA00004907.

33. CareDx denies infringement of the '658 patent, denies that Exhibit D is evidence of or exemplary of infringement, and lacks information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 33 of the Natera Complaint and therefore denies them.

34. CareDx denies that it has made use of any technology patented by Natera, including the subject matter described and claimed in the '658 patent, and denies that Natera is entitled to any of the forms of relief enumerated in paragraph 34 of the Natera Complaint. To the extent Paragraph 34 contains any additional allegations, CareDx lacks information sufficient to form a belief as to their truth and therefore denies them.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 10,526,658

35. CareDx responds to each factual allegation incorporated by reference into Paragraph 35 in the manner set forth above with respect to each corresponding factual allegation.

36. CareDx denies that it infringes the '658 patent under any theory of infringement, and denies that it needs authorization from Natera in order to market and sell AlloSure. CareDx denies that Exhibit D is evidence of or exemplary of infringement. To the extent there are any remaining allegations in paragraph 36 of the Complaint, CareDx lacks information sufficient to form a belief as to the truth of them and therefore denies them.

37. CareDx denies that the allegations within Exhibit D constitute allegations within the meaning of the Federal Rules of Civil Procedure and that any response is required. To the extent a response is required, CareDx denies infringement and—as is established by documents CareDx has produced in this litigation such as CAREDXNA00004885- CAREDXNA00004907—denies that AlloSure operates in the manner alleged.

RESPONSE TO PRAYER FOR RELIEF

CareDx denies that Natera is entitled to a judgment of infringement, an injunction, damages, or any relief whatsoever.

AFFIRMATIVE DEFENSES

CareDx hereby sets forth defenses to the Natera Complaint in order to place Natera on notice regarding applicable defenses. By listing any matter as a defense herein, CareDx does not assume the burden of proving any matter upon which Natera, or any other party, bears the burden of proof under applicable law.

FIRST DEFENSE – NON-INFRINGEMENT

1. CareDx has not infringed, and is not infringing, any valid claim of the '658 patent, either literally or under the doctrine of equivalents. CareDx's non-infringement is established by documents already produced in this litigation, such as CAREDXNA00004885-CAREDXNA00004907.

SECOND DEFENSE – INVALIDITY

2. The asserted claims of the '658 patent are invalid for failing to comply with one or more of the requirements for patentability under, including but not limited to, 35 U.S.C. §§ 101, 103, 112, and the judicial doctrine of obviousness-type double patenting.

THIRD DEFENSE – PROSECUTION LACHES

3. Natera's '658 patent infringement claims are barred under the doctrine of prosecution laches.

FOURTH DEFENSE – 35 U.S.C. § 287

4. Natera's '658 patent infringement claims and Prayer for Relief are limited by 35 U.S.C. § 287.

FIFTH DEFENSE – ADEQUATE REMEDY AT LAW

5. Natera has an adequate remedy at law and the alleged injury to Natera is not immediate or irreparable. Accordingly, Natera is not entitled to injunctive relief even if it were able to establish liability.

SIXTH DEFENSE – NO EXCEPTIONAL CASE

6. CareDx has not engaged in any conduct that would make this an exceptional case or that would entitle Natera to an award of attorneys' fees.

SEVENTH AFFIRMATIVE DEFENSE – FAILURE TO STATE A CLAIM

7. Natera's Complaint fails to state a claim upon which relief may be granted.

Dated: March 4, 2020

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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